

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application)	
Inventor: R. Christopher deCharms)	Examiner: Ruth S. Smith
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Application No.: 10/066,004)	Art Unit: 3737
)	
Filed: January 30, 2002)	Confirmation No.: 7144
)	
Title: METHODS FOR PHYSIOLOGICAL)	Customer No.: 021971
MONITORING, TRAINING,)	
EXERCISE AND REGULATION)	
)	

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER 37 C.F.R. § 1.132

I, R. Alison Adcock, M.D., Ph.D., hereby declare, based on information and belief:

I currently serve as Assistant Professor, Psychiatry and Behavioral Sciences at Duke University, and I am a part of the Core Faculty, Center for Cognitive Neuroscience on the faculty at Duke University. I have extensive experience in neuroimaging, which forms a major basis for the work in my laboratory, and also for cognitive control and behavioral therapy methods.

I would like to comment on the patent application by Christopher deCharms directed to using fMRI for measuring brain activation in order to guide cognitive tasks or train subjects to control their brain activation. I am familiar with the patent claims by Dr. deCharms. I am also very familiar with the fields of fMRI and cognitive science, as well as the clinical field of psychotherapy, in which I am trained. I am in a good position to evaluate the novelty or obviousness of this approach in comparison with the prior literature and art in the field. I have no financial interest in Omneuron or other sources of potential conflict of interest.

Based upon my knowledge of this field, I believe that at the time that this application was originally submitted, January 30, 2001, a person with technical training in brain imaging, PET or fMRI would not have had a reasonable expectation that the methods described in the claims of Dr. deCharms would have succeeded. Many new approaches may appear clear or obvious in hindsight once they have succeeded. It was not at all obvious at that time that it would make sense to try to guide the

cognitive processes of a subject while using neuroimaging or fMRI information from the subject's own brain.

In the field of neural plasticity and cognitive training, an area in which I have been working in for over a decade, the question of how to direct a subject to control particular brain systems had been an important topic of discussion for many years, one that my colleagues and I had discussed from many different perspectives. Had it been obvious that it was possible to shape behavior, guide a subject's cognitive processes, or train control over brain activation using information derived from neuroimaging or fMRI, it would likely have been done earlier because fMRI had already been in practice for ten years by 2001.

It was not at all clear at the time whether or how one could use neuroimaging-based information to guide the cognitive processes in a subject or to train a subject to control their brain activation. There are many substantial differences between neuroimaging modalities such as fMRI and PET vs. earlier physiological measurement approaches such as EEG. Although it may seem straightforward in hindsight, it was not apparent to people at the time that one could successfully use neuroimaging in any way analogous to feedback approaches that had been tried with other modalities such as EEG. In addition, at the time it was not at all clear how one would go about doing it (e.g., what kinds of analysis to use, whether to use brain images or use information from a particular brain region or region of interest, how rapidly to show the feedback information, how to instruct subjects, etc.). Prior to the experiments of Dr. deCharms that ultimately proved the point, it was not clear that this approach would work given the variability in neuroimaging data, the inherent delays, and the uncertainty regarding whether subjects could readily interpret and figure out how to meaningfully use this information to control their cognitive processes, control brain activation, or for other purposes. Prior investigators, such as Voyvodic et al., had performed real time fMRI while instructing subjects to perform tasks in order to map brain activation more quickly. However, they had not made the conceptual leap to "close the loop": To use the neuroimaging-derived information itself as the basis for controlling subject instructions, behavior or brain activation.

I, R. Alison Adcock, declare that all statements made herein are true to the best of my knowledge, or if made upon information and belief, are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Dated: 9/25/07

By: R. Alison Adcock

R. Alison Adcock, M.D., Ph.D.